CLAIMS

1. A method for differentiating between two states of an analyte that exists in a plurality of forms, which states differ from one another in the nature and/or amount of one or more forms present therein, in which method a sample, or contemporaneous samples, containing the analyte are: (a) subjected to a two step specific binding assay utilising a first binding agent specific for the analyte and a labelled second binding agent specific for the analyte to provide a first test signal proportional to the amount of analyte present in the sample, wherein, in a first step of the two step assay, the analyte is contacted with the first binding agent to form a first binding agent/analyte complex, and in a second step of the two step assay, the first binding agent/analyte complex is contacted with the labelled second binding agent, to form a first binding agent/analyte/second biding agent complex; and (b) said sample or samples are also subjected to a one step specific binding assay utilising the same pair of analyte-specific binding agents, in which one step assay the analyte is contacted with both first and second binding agents substantially simultaneously, to form the first binding agent/analyte/second binding agent complex, to provide a second test signal proportional to the amount of analyte present in the test sample; and wherein at least one member of said pair of binding agents having a different specificity for each of said two states of said analyte, and the first test signal is compared to the second test signal.

2. A method according to claim 1, wherein each of said first and second binding agents has a different specificity for each of said two states of said analyte.

3. A method according to claim 1 or claim 2, wherein a combined test result is expressed as a ratio of the two test signals.

4. A method according to claim 3, wherein the ratio of the two test signals is compared to a standard ratio for one or other of the two states to determine in which state the sample analyte exists.

5. A method according to any one of the preceding claims, wherein the analyte is a gonadotrophin.

6. A method according to claim 5, wherein the analyte is follicle stimulating hormone (FSH).

7. A method according to any one of the preceding claims, wherein both first and second binding agents are antibodies.

8. A method according to claim 7, wherein each binding agent is a monoclonal antibody.

9. A method according to any one of the preceding claims, wherein in the two step assay the sample is incubated with a solid phase on which is immobilised the first binding agent, and thereafter following a step to remove unbound analyte the solid phase is incubated with the labelled second binding agent.

10. A method according to any one of the preceding claims, wherein in the one step assay the sample is simultaneously incubated with a solid phase on which the first binding agent is immobilised and with the labelled second binding agent in solution or suspension.

11. A method according to any one of claims 1-9, wherein in the one step assay the sample is simultaneously incubated with the first binding agent in solution or suspension and with the labelled second binding agent in solution or suspension, and the first binding agent is thereafter immobilised on a solid phase.

12. A method according to claim 10 or 11, wherein immobilisation of the first binding agent on the solid phase is effected through a specific binding reaction.

13. A method according to claim 12, wherein the specific binding reaction is an avidin-biotin interaction.

14. A method for differentiating between an FSH sample indicative of a present or impending fertile status of the human ovulation cycle and an FSH sample indicative of a present or impending infertile status of the human ovulation cycle, substantially as hereinbefore described.

15. An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00032004.

16. An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00032005.

17. A method according to any one of claims 1 to 14, wherein the labelled second binding agent is an antibody as claimed in claim 15 and the first binding agent is an antibody as claimed in claim 16.

18. A test device for testing a body fluid sample obtained from a human subject, the device comprising a first analyte-responsive (preferably gonadotrophin-responsive) signal-producing means that provides a readable signal by means of a two step assay as described herein, and a second analyte-responsive (preferably gonadotrophin-responsive) signal-producing means that provides a readable signal by means of a one step assay.

19. A test kit comprising a test device according to claim 18, and instructions for use in a method according to any one of claims 1-14 or claim 17.

20. A test kit for performing a method according to any one of claims 1-14 or claim 17, the kit comprising a first test device having analyte-responsive (preferably gonadotrophin-responsive) signal-producing means that provides a readable signal by means of a two step assay, and a second test device having second analyte-responsive (preferably gonadotrophin-responsive) signal-producing means that provides a readable signal by means of a one step assay.